Proposed Maximum Residue Limit PMRL2014-52

Fludioxonil

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing to establish maximum residue limits (MRLs) for fludioxonil on pineapples, tomatoes and citrus fruits (CG 10-revised) to permit the import and sale of foods containing such residues.

Fludixonil is a fungicide currently registered in Canada for use on various commodities.

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when fludioxonil is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally established as an MRL on the corresponding imported commodity. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for fludioxonil is being conducted via this document (see Next Steps). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace or be added to the MRLs already established for fludioxonil, are as follows.

Table 1 Proposed Maximum Residue Limits for Fludioxonil

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile	20	Pineapples
		10	Citrus fruits (CG 10-revised)[2]
		5.0	Tomatoes[3]

[1] ppm = parts per million
[2] The currently established MRL of 10 ppm for citrus fruits (CG 10) will be extended to the complete citrus fruits (CG 10revised);
[3] The proposed MRL of 5.0 ppm for tomatoes will replace the existing MRL of 0.5 ppm.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

Table 2 compares the MRLs proposed for fludioxonil in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Pineapples	20	20	None Established
Tomatoes	5.0	5.0	0.5

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fludioxonil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

Residue data for fludioxonil in pineapples, tomatoes, oranges and grapefruits were submitted to support the maximum residue limits on imported pineapples, tomatoes and citrus fruits (CG 10-revised). Previously reviewed residue data from field trials conducted in/on oranges, lemons and grapefruits were reassessed in the framework of this petition. In addition, a processing study in treated pineapple was reviewed and processing studies in treated orange, lemon and tomato were also reassessed to determine the potential for concentration of residues of fludioxonil into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fludioxonil was based upon the residues observed in crop commodities treated according to label directions in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for imported fludioxonil.

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method (Total Application Rate)	Days After Application (day)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
Pineapples	Dip (30.4 g a.i./50L) + spray (434 g a.i./50L)	0	4.41	6.50	0.96-fold (juice)
	Drench (30.4 g a.i./50L) + spray (434 g a.i./50L)	0	4.57	7.18	
Tomatoes	Dip (54.4-57.6 g a.i./100 L)	0	0.275	1.19	1.1-fold (paste) 0.3-fold (puree)
	Drench(57.4-57.5 g a.i./100 L)	0	0.237	1.16	
	Packing-line spray (217.7-218.6 g a.i./50 tons of fruit)	0	0.170	1.97	
Oranges	Dip (600 g a.i./100 L)	0	0.70	1.10	0.03-fold (juice) 69-fold (oil) 1.9-fold (peel)
	Low volume (0.45 kg a.i./250 tons fruit)	0	0.37	0.74	
	Drench (30 g a.i./100 L) + low volume (0.23 kg a.i./250 tons fruit)	0	0.32	0.53	
	Drench (60 g a.i./100 L) + low volume (0.45 kg a.i./250 tons fruit)	0	0.75	0.86	
	Low volume (0.45 kg a.i./250 tons fruit)	0	0.62	0.85	
	Low volume (0.91 kg a.i./250 tons fruit)	0	0.90	1.00	
	Dip/storage wax + dip (240 g a.i./100 L)	0	1.40	2.96	
	Spray/storage wax + spray/storage wax (1.8 kg a.i./250 tons fruit)	0	0.41	0.70	
Grapefruits	Dip (60 g a.i./100 L)	0	0.60	0.95	0.03-fold (juice)

Commodity	Application Method (Total Application Rate)	Days After Application (day)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
	Low volume (0.45 kg a.i./250 tons fruit)	0	0.07	0.67	69-fold (oil) 1.9-fold (peel)
	Drench (30 g a.i./100 L) + low volume (0.23 kg a.i./250 tons fruit)	0	0.14	0.34	
	Drench (60 g a.i./100 L) + low volume (0.45 kg a.i./250 tons fruit)	0	0.17	0.59	
	Low volume (0.45 kg a.i./250 tons fruit)	0	0.05	0.92	
	Low volume (0.91 kg a.i./250 tons fruit)	0	1.50	1.50	
	Dip/storage wax + dip (240 g a.i./100 L)	0	4.25	6.85	
	Spray/storage wax + spray/storage wax (1.8 kg a.i./250 tons fruit)	0	0.49	0.55	
Lemons	Dip/storage wax + dip (240 g a.i./100 L)	0	2.01	4.28	0.03-fold (juice) 69-fold (oil) 1.9-fold (peel)
	Spray/storage wax + spray/storage wax (1.8 kg a.i./250 tons fruit)	0	0.65	1.01	

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of fludioxonil. Residues of fludioxonil in these imported crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.